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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,099	11/29/2001	Mary Mowrey-McKee	LP/V-31594/A	3645
31781	7590	11/03/2005	EXAMINER	
CIBA VISION CORPORATION PATENT DEPARTMENT 11460 JOHNS CREEK PARKWAY DULUTH, GA 30097-1556			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 11/03/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,099

Applicant(s)

MOWREY-MCKEE ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 200510.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of amendment filed on August 1, 2005. Claims 1-8 and 10-18 are pending. Claim rejections made in the previous Office action dated January 27, 2005 are withdrawn in view of applicants' remarks. New rejections are made in view of further search and consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 10-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "polyol" in claim 1 and 18 is not found in the original disclosure. Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) . In this case, however, applicants disclose only glycerol and mannitol in the specification. Applicants do not have support for the entire genus of polyol as the present claims recite.

The remaining claims are rejected as they depend on base claims that are directed to subject matter that are not supported by the original disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. (US 5474700).

Griffin et al. disclose protease samples that are treated in hydrogen peroxide (microbicide of claim 6) and 20 mM of Bis Tris propane buffer and sodium chloride (tonicity agent of claims 14 and 15). See Example 5; instant claims 1, 2, 4-6, 14, and 15.

The term “for disinfecting a contact lens” is a preamble that recites the intended future use and purpose of the claimed solution. See MPEP § 2111.02. Thus no patentable weights are given to this phrase.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Bruij et al. (US 6162393).

De Bruij et al. teach making a contact lens and ophthalmic solutions comprising benzyldimethyl {2-2-(p-1,1,3,3-tetramethylbutylphenoxy)ethoxy}ethyl ammonium chloride (a disinfectant, benzethonium chloride), in an isotonic diluent buffered with a physiologically acceptable buffer to a physiologically natural range. See abstract. See instant claim 6. To enhance compatibility with the eye, the reference teaches adding, among others, nitrogen containing buffer solution such as BIS-Tris Propane is a well-known buffer for contact lens and ophthalmic solutions which makes the pH of the composition 6.5-8.5. See col. 4, lines 19 – 37. The reference also teaches tonicity agent, particularly sodium chloride, viscosity building agents such as polyvinylpyrrolidone and carboxymethyl cellulose, surfactants such as polyoxyethylenes, and sequestering agents such as EDTA. See col. 4, lines 38 – 47. See instant claims 10-17. While the molar amount of the buffer is not specifically taught, the reference teaches the physiological pH that is required in the final solution. Thus adjusting the concentration of the buffer solution to meet the final pH limitation would have been within the skill of the art. See instant claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of De Bruij et al. by combining the ingredients of the recited components (disinfecting agents, Bis Tris Propane, osmotic agents, viscosity building agents, sequestering agents) as suggested by the reference with the motivation to make a contact lens and ophthalmic solutions to enhance compatibility with the eye.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over De Bruiju et al. (US 6162393) as applied to claims 1-6, 8, 10-17 as above, and further in view of Mowrey-McKee et al. (US 5500186).

De Bruiju et al. fail to teach the microbicide of instant claim 7.

Mowrey-McKee et al. teach a method of disinfecting a contact lens in an aqueous solution comprising an effective amount of tromethamine and a microbicide selected from, among others, polyhexamethylene biguanide and alexidine. See col. 2, line 66-col. 3, line 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of De Bruiju et al. by substituting the microbicide there with polyhexamethylene biguanide or alexidine as motivated by Mowrey-McKee et al. because the latter reference teaches that those microbicides are effective and well known contact lens disinfectants. The skilled artisan would have had a reasonable expectation of successfully producing a contact lens solution that is similarly provide anti-microbial cleaning and compatibility to eyes.

Applicants' data in specification p. 10-13 have been considered. The data there shows the antimicrobial effects of Bis-Tris buffer in combination of PHBH and alexidine in specific concentration. Claims 1 and 7 are not limited to the concentration of the microbicide or the buffer component that lead to the increased antimicrobial activities as shown in the specification. Thus claims 1 and 7 do not reflect the scope of the evidence of the record.

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 10-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 7:00AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER